Remarks

The Office Action of October 4, 2004 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is earnestly requested. Claims 1-65 are pending in the application, claims 24 and 41 being amended by this Amendment. The amendment of claims 24 and 41 is supported by the original claims and throughout the specification; no new matter has been added.

In view of the above amendments and the following remarks, favorable reconsideration of the outstanding office action is respectfully requested.

Restriction Requirement

The Examiner has made a restriction requirement and has identified eight (8) groups as follows:

Group I - recited in claims 1-2, 6-11, 26-31 and 47-50.

Group II - recited in claims 3-4, 12-13, 16-23, 32-36 and 39-40.

Group III - recited in claims 14-15 and 37-38.

Group IV - recited in claims 24-25 and 41-46.

Group V - recited in claim 51.

Group VI - recited in claims 52-57.

Group VII - recited in claims 58-61.

Group VIII - recited in claims 62-65.

The Examiner states that claim 5 links Groups 1 and II and that, therefore, if Group I or II is elected and claim 5 is found allowable, then the claims in Groups I and II will be examined on the merits. The Examiner also states that the requirement for restriction between product and process claims may also be rejoined according to the provisions of MPEP 821.04.

Applicant hereby elects Group I, claims 1-2, 6-11, 26-31 and 47-50 for continued examination. Applicant also amends claims 24 and 41 to depend from claim 3, as helpfully suggested by the Examiner. Applicant respectfully submits that if claim 3 is examined and found to be allowable, then the claims 24-25 and 41-46 should be rejoined.

The requirement for restriction, as best understood, is respectfully traversed.

The MPEP states the following with regard to stating a *prima facie* case of restriction between patentably distinct inventions:

> *"There are two criteria for a proper requirement for restriction between patentably distinct inventions:*
>
> *1) The inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(i)); and*
>
> *2) There must be a serious burden on the examiner if restriction is not required (see MPEP 803.02, 806.04(a) - 806.04(j), 808.01(a) and 808.02).*
>
> *GUIDELINES*
>
> *Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the requirement in most cases. Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement...For purposes of the initial requirement a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02."*

The claims in all of the Groups are related in that they all recite the same protein molecules or the DNA molecules encoding them. It is respectfully submitted that the Examiner did not make a *prima facie* case to support the restriction requirement. Both criteria for restriction must be established and the Examiner has not properly shown any undue burden or distinctiveness in the claimed inventions. Furthermore, distinct inventions do not create a burden on the Examiner that is sufficient to justify a restriction requirement, without a showing of the need for separate searches. Even if some of the inventions are classified separately, a thorough search of the prior art for any one of the inventions should include the classes and subclasses of the other inventions.

Furthermore, the MPEP (811) states that the restriction shall be complete. Applicant has been denied a chance to properly respond to the restriction, because it was not stated completely in the office action.

The Examiner maintains that inventions I and II are unrelated, because they are alleged to "encompass two different products, DNA and protein." However, the proper legal standard requires the Examiner to show that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04 and 808.01). The Examiner has not shown the need for separate searches for Groups I and II. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, as the DNA molecules in Group I encode the protein molecules in Group II. Furthermore, the Examiner has not properly alleged, much less shown, that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Rather, the Examiner merely asserts that the inventions encompass two different products, DNA and protein, which does not address the foregoing facts required to support a restriction requirement. It is respectfully submitted that the requirement for restriction between the claims of Group I and Group II is thus overcome.

The Examiner states that inventions II and III are related as sub-combinations, but maintains that restriction is nevertheless warranted, because it is alleged that "invention II has a separate utility, such as an antigen to make antibodies, which does not use or require use of a cytokine, or for use in protein kinetics studies." The Examiner has not shown the need for separate searches for Groups I and II. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, particularly since all of the claims in Group II depend from claims 12 and 32 of Group II. Therefore, if claims 12 and 32 of Group II are allowed, then the dependent claims in Group II necessarily must also be allowed. Furthermore, the Examiner has not properly shown that the inventions are separately useable. Indeed, use of the invention to induce the production of antibodies is not substantially different from using the invention as a vaccine, since use as a vaccine would induce the production of antibodies. It is respectfully submitted that the requirement for restriction between the claims of Group II and Group III is thus overcome.

The Examiner states that inventions I and V are related as product and process of use, but maintains that restriction is nevertheless warranted, because it is alleged that "the method of diagnosis can be accomplished with other forms of polynucleotides and methodology than that of Group I." The Examiner has not shown the need for separate searches for Groups I and V. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, particularly since the DNA molecules of the claims in Group I are identical to the DNA molecules of the claims in Group V. Furthermore, the Examiner has not properly shown that the method of diagnosis can be accomplished with other forms of polynucleotides and methodology than that of Group I. Rather, the Examiner merely makes such assertion, which is wholly unsupported. It is respectfully submitted that the requirement for restriction between the claims of Group I and Group V is thus overcome.

The Examiner maintains that inventions I and VI-VIII are unrelated, because they are alleged to "encompass a product and method that do not require each other." However, the proper legal standard requires the Examiner to show that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04 and 808.01). The Examiner has not shown the need for separate searches for Groups I and VI-VIII. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, as the protein molecules recited in the claims of Group I are identical to the protein molecules recited in the claims of Groups VI-VIII. Furthermore, the Examiner has not properly alleged, much less shown, that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Rather, the Examiner merely asserts that the inventions encompass a product and method that do not require each other, which does not address the foregoing facts required to support a restriction requirement. It is respectfully submitted that the requirement for restriction between the claims of Group I and Groups VI-VIII is thus overcome.

The Examiner states that inventions II and IV are related as product and process of use, but maintains that restriction is nevertheless warranted, because it is alleged that "the protein can be used as a vaccine, and the method of screening for epitopes can be

accomplished with other methodology known in the art, such as screening naturally occurring antibodies/immunity." The Examiner has not shown the need for separate searches for Groups II and IV. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, particularly since the protein molecules of the claims in Group II are identical to the protein molecules of the claims in Group IV. Furthermore, the Examiner has not properly shown that the method of screening for epitopes can be accomplished with other methodology known in the art. Rather, the Examiner merely makes such assertion, which is wholly unsupported. It is respectfully submitted that the requirement for restriction between the claims of Group I and Group V is thus overcome. Nevertheless, Applicant hereby amends claims 24 and 41, thus bringing the claims in Group IV within the scope of the claims in Group II for rejoinder, as helpfully suggested by the Examiner.

The Examiner maintains that inventions II and VI-VIII are unrelated, because they are alleged to "encompass a product and methods that do not require each other." However, the proper legal standard requires the Examiner to show that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04 and 808.01). The Examiner has not shown the need for separate searches for Groups II and VI-VIII. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, as the protein molecules recited in the claims of Group II are identical to the protein molecules recited in the claims of Groups VI-VIII. Furthermore, the Examiner has not properly alleged, much less shown, that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Rather, the Examiner merely asserts that the inventions encompass a product and methods that do not require each other, which does not address the foregoing facts required to support a restriction requirement. It is respectfully submitted that the requirement for restriction between the claims of Group II and Groups VI-VIII is thus overcome.

The Examiner maintains that inventions IV-VIII are unrelated, because they are alleged to encompass "methods that require different materials and method steps to practice." However, the proper legal standard requires the Examiner to show that the inventions are not

disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04 and 808.01). The Examiner has not shown the need for separate searches for Groups IV-VIII. Even if some of the inventions are classified separately, a thorough search of the prior art for either of the inventions should include the classes and subclasses of the other inventions, as the protein molecules recited in the claims of Groups IV-VIII are identical. Furthermore, the Examiner has not properly alleged, much less shown, that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Rather, the Examiner merely asserts that the inventions encompass methods that require different materials and method steps to practice, which does not address the foregoing facts required to support a restriction requirement. It is respectfully submitted that the requirement for restriction between the claims of Groups IV-VIII is thus overcome.

Applicant thus requests that the restriction requirement be withdrawn. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

Conclusion

Based upon the above amendments, remarks, and papers of record, Applicants believe the pending claims of the above-captioned application are in allowable form and patentable over the prior art of record. Applicants respectfully request reconsideration of the pending claims 1-65 and a prompt Notice of Allowance thereon.

Applicants believe that no extension of time is necessary to make this Response timely. Should Applicants be in error, Applicants respectfully requests that the Office grant such time extension pursuant to 37 C.F.R. § 1.136(a) as necessary to make this Response timely, and hereby authorizes the Office to charge any necessary fee or surcharge with respect to said time extension to the deposit account of the undersigned firm of attorneys, **Deposit Account 50-0289**.

Please direct any questions or comments to Thomas T. Aquilla at (607) 256-7330.

Respectfully submitted,

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